

WHAT IS CLAIMED IS:

1. A controlled release oxycodone formulation for oral administration to human patients, comprising from about 10 mg to about 160 mg oxycodone, based on the hydrochloride salt, said formulation providing a mean maximum plasma concentration of oxycodone from about 6 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration, said formulation providing a desired analgesic effect for at least about 12 hours.
2. The controlled release oxycodone formulation of claim 1, comprising from about 10 to about 40 mg oxycodone based on the hydrochloride salt, said formulation providing a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration.
3. The controlled release oxycodone formulation of claim 1, comprising from about 40 mg to about 160 mg oxycodone based on the hydrochloride salt, said formulation providing a mean maximum plasma concentration of oxycodone from about 60 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration.

4. The solid controlled release oxycodone formulation of claim 1, comprising
oxycodone hydrochloride dispersed in an effective amount of a controlled release matrix selected
5 from the group consisting of hydrophilic polymers, hydrophobic polymers, digestible substituted or unsubstituted hydrocarbons having from about 8 to about 50 carbon atoms, polyalkylene glycols, and mixtures of any of the foregoing, and a suitable amount of a suitable
10 pharmaceutical diluent.

5. The solid controlled release oxycodone formulation of claim 1, comprising:

(a) an analgesically effective amount of
15 spheroids comprising oxycodone or a salt thereof and either a spheronising agent or an acrylic polymer or copolymer, such that the total dosage of oxycodone in said dosage form is from about 10 to about 160 mg based on the hydrochloride salt; and

20 (b) a film coating on said spheroids which controls the release of the oxycodone or oxycodone salt at a controlled rate in an aqueous medium, wherein said composition provides an in vitro dissolution rate of the dosage form.

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6. The controlled release oxycodone formulation of claim 1, comprising a tablet wherein said oxycodone is dispersed in a controlled release matrix.

30 7. The controlled release oxycodone formulation of claim 1, wherein said oxycodone is in the form of the hydrochloride salt.

8. A method for substantially reducing the range in daily dosages required to control pain in human patients, comprising administering an oral controlled release dosage formulation comprising from about 10 to about 160 mg oxycodone or a salt thereof based on the hydrochloride salt which provides a mean maximum plasma concentration of oxycodone from about 6 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration.
- 10 9. A method for substantially reducing the range in daily dosages required to control pain in substantially all human patients, comprising administering an oral solid controlled release dosage formulation comprising from about 10 mg to about 40 mg oxycodone or a salt thereof based on the hydrochloride salt which provides a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of up to about 2 to about 4.5 hours after administration.
- 15 10. A method for substantially reducing the range in daily dosages required to control pain in substantially all human patients, comprising administering an oral solid controlled release dosage formulation comprising from about 40 mg to about 160 mg oxycodone or a salt thereof based on the hydrochloride salt which provides a mean maximum plasma concentration of oxycodone from about 60 to about 240 ng/ml from a mean of up to about 2 to about 4.5 hours after administration.